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April 29, 2005

VIA HAND DELIVERY

Division of Dockets Management Branch
U.S. Food and Drug Administration
Department of Health & Human Services, rm. 1-23
5630 Fishers Lane, Room 1061
Rockville, MD 20852

PETITION FOR RECONSIDERATION

Docket No. 2003P-0159

The undersigned, on behalf of Wyeth Pharmaceuticals ("Wyeth"), submits this petition for reconsideration of the March 30, 2005 decision of the Commissioner of Food and Drugs in Docket No. 2003P-0159(PAV1).

A. *Decision involved*

By letter of March 30, 2005,[1] FDA approved Lachman Consultant Services, Inc.'s Suitability Petition, submitted April 16, 2003 (2003P-0159(CP1)) (the "Suitability Petition"). FDA's decision permits the filing of an abbreviated new drug application (ANDA) for venlafaxine hydrochloride extended-release tablets, 37.5 mg, 75 mg, and 150 mg. The decision referenced comments submitted to the docket by Wyeth, but provided no explanation or reasoning behind the agency's rejection of those comments.

B. *Action requested*

The undersigned requests that, upon reconsideration, the Commissioner deny the Suitability Petition and refuse to accept for filing any ANDA for venlafaxine hydrochloride

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[1] Letter from FDA to Lachman Consultant Services, Inc. (2003P-0159(PAV1)), at 1 (March 30, 2005)

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extended release tablets. If FDA declines to reverse its approval of the Suitability Petition, Wyeth requests that the agency provide a detailed explanation of its views on the issues raised by the August 28, 2003 comments submitted by Wyeth (the "Wyeth Comment").[2]

C. *Statement of Grounds*

Under FDA's regulations, reconsideration of agency action on a citizen petition is warranted where "relevant information or views contained in the administrative record were not previously or not adequately considered."[3] Here, FDA's March 30, 2005 approval of the Suitability Petition fails to address, except in the most cursory way, the serious issues raised by the Wyeth Comment. The Wyeth Comment provided over nine pages of scientific analysis and data pointing to various safety and effectiveness issues that potentially would be raised by a tablet formulation of extended release venlafaxine hydrochloride. These include the potential for increased nausea and vomiting, significant intra-subject variations in bioavailability, and patient compliance issues.

Despite these important public health issues, the only mention of the Wyeth Comment in FDA's approval letter is the statement that "[w]e also refer to the comments dated August 28, 2003, and April 8, 2004, submitted by Wyeth Pharmaceuticals."[4] Instead of providing insight into FDA's consideration or opinions regarding the issues raised by the Wyeth Comment, FDA explained its decision through what amounts to a tautological recitation of the underlying statute:

> The FDA finds that the change in dosage form for the specific proposed drug products does not pose questions of safety or effectiveness because the uses, dose, and route of administration of the proposed drug products are the same as that of the listed drug products. The FDA concludes, therefore, that clinical investigations are not necessary to show safety or effectiveness in this instance. In addition, if shown to meet bioavailability

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[2] Letter from Wyeth Pharmaceuticals to FDA (2003P-0159(C1)) (August 28, 2003) (Attached hereto as Exhibit A).

[3] 21 C.F.R. § 10.33(d)(1).

[4] Letter from FDA to Lachman Consultant Services, Inc., at 1 (March 30, 2005) (hereinafter "March 30, 2005 Approval Letter"). Wyeth's April 8, 2004 comment related to Lachman's request for waiver of the requirements of the Pediatric Research Equity Act of 2003, and is not relevant to this Petition for Reconsideration.

> requirements, the proposed drug products can be expected to have the same therapeutic effect as the listed reference drug products.[5]

These conclusory statements do not constitute genuine consideration of the issues Wyeth placed into the record.[6]

It is a fundamental principle of administrative law that administrative agencies must provide reasoned and complete explanations for their decisions. As the United States Supreme Court has stated on numerous occasions, when rendering an administrative decision a federal agency must "examine the relevant data and *articulate a satisfactory explanation for its action* including a 'rational connection between the facts found and the choice made.'"[7] Without such an explanation, a court reviewing the decision would be unable to determine if the agency's decision was "based on a consideration of the relevant factors and whether there has been a clear error of judgment."[8]

FDA acknowledges its duty to provide a reasoned explanation for its decisions in its administrative proceedings regulations at 21 C.F.R. Part 10.[9] FDA's regulations specifically provide that administrative reconsideration is appropriate when the agency fails to consider adequately relevant information in the administrative record.[10] Where, as here, FDA fails to set

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[5] March 30, 2005 Approval Letter, at 2.

[6] FDA's analysis of information in the administrative record that is adverse to a given citizen petition (including suitability petitions) is at least as important to FDA's final decision as its analysis of favorable information in the record. As pointed out in FDA's preamble to its administrative procedures proposed rule, "in making many administrative decisions, the Commissioner will often choose between competing versions of the 'facts.' . . . [A] decision favorable to a petition that reflects a review of information and arguments both supportive of and adverse to the petition is likely to be credible, and thus ultimately more supportable, than a decision reached on the basis only of supportive information." 42 Fed. Reg. 4680, 4686 (January 25, 1977).

[7] *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

[8] *Bowman Transportation, Inc. v. Arkansas Best Freight System, Inc.*, 419 U.S. 281, 285 (1974).

[9] FDA's suitability petition regulations at 21 C.F.R. § 314.93 state that a suitability petition, such as the one at issue here, is filed as a citizen petition, and is thus subject to Part 10. *See* 21 C.F.R. § 314.93(c).

[10] *See supra* note 3.

forth its consideration of material issues in the public record, there is no way to determine whether FDA has met these standards. The only conclusion that can be reached on the available record, therefore, is that FDA did not adequately consider the Wyeth Comment. Reconsideration is warranted on that basis.

D. *Conclusion*

Based on the above, Wyeth hereby petitions FDA to reverse its March 30, 2005 approval of the Suitability Petition. If the agency declines to reverse its approval, Wyeth requests that the agency provide a detailed explanation for its rejection of the Wyeth Comment.

Respectfully submitted,

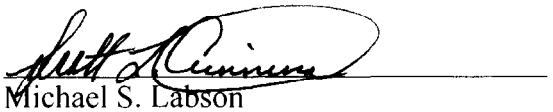

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Exhibit A